Europäisches Patentamt

European Patent Office

Office européen des brevets



EP 0 647 147 B1 (11)

EUROPEAN PATENT SPECIFICATION (12)

(45) Date of publication and mention of the grant of the patent: 15.03.2000 Bulletin 2000/11

(21) Application number: 93913814.5

(22) Date of filing: 12.05.1993

(51) Int. Cl.⁷: **A61M 29/00**

(86) International application number: PCT/US93/04313

(87) International publication number: WO 94/00178 (06.01.1994 Gazette 1994/02)

(54) CATHETER WITH EXPANDABLE WIRE MESH TIP

KATHETER MIT AUSDEHNBARER MASCHENDRAHTSPITZE CATHETER POURVU D'UNE POINTE A TREILLIS EN FIL METALLIQUE EXTENSIBLE

(84) Designated Contracting States: AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT SE

(30) Priority: 26.06.1992 US 904793

(43) Date of publication of application: 12.04.1995 Bulletin 1995/15

(73) Proprietor: SCHNEIDER (USA) INC. Plymouth, Minnesota 55442 (US)

(72) Inventors:

• LAPTEWICZ, Joseph, E. Eden Prairie, MN (US)

· YUREK, Matthew, T. S. Bloomington, MN (US)

• SILVESTRINI, Thomas, A. Santa Clara, CA (US)

(74) Representative:

Walters, Frederick James et al **Urquhart-Dykes & Lord** 91 Wimpole Street London W1M 8AH (GB)

(56) References cited:

EP-A- 0 416 662 DE-U-9109006 US-A- 4 643 186 US-A- 4 873 978

US-A- 5 053 048

B1 647 147 0 믑

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] Catheters having inflatable balloons mounted on their distal ends are a commonly used apparatus for entering blood vessels to expand and open strictures at 5 remote sites in a non-invasive manner.

[0002] In conventional balloon catheters, vessel expansion is achieved by inflating the balloon on the catheter tip at the site of the obstruction. The balloon expands radially outward, thereby expanding the place in the blood vessel where it is located.

[0003] One disadvantage of the conventional balloon catheter is that blood flow through the lumen of the vessel in which the balloon is to be inflated, which is already severely reduced because of the stricture, is momentarily completely cut-off when the balloon is inflated and exerting pressure against the stricture-causing mass and/or wall of the vessel. If such a condition is maintained for an extended period of time it is possible that damage to or necrosis of the tissue material of the vessel wall may occur.

[0004] Accurate control of the extent of inflation of the balloon may also be difficult to achieve in some circumstances with conventional balloon catheters. If inflation is not carefully monitored and controlled, it is possible to 25 overinflate the balloon which in turn may cause a stretching and weakening of the vessel wall.

In the particular application of balloon cathe-[0005] ters to angioplasty, moreover, there is a possibility, which occurs at a frequency on the order of about 5% of 30 the cases, of the abrupt reclosure of an expanded artery after balloon angioplasty. This is generally due to a dissection of the arterial wall obstructing the lumen, to elastic recoil of the arterial wall, or to spontaneous spasm of the arterial wall.

Prior Art

[0006] DE-U-9109006 upon which the preamble of claim 1 is based describes an angioplasty catheter in 40 which a mesh is used to hold open the blood vessel. The mesh has a coil structure which has an intrinsic expanded configuration. The catheter comprises an outer retractable sheath which will keep the mesh in a tight, reduced configuration before deployment. The sheath is removed to allow the mesh to expand.

[0007] EP-A-0416662 describes a vascular catheter having an expandable cage mounted on the distal end of a tubular member which may be radially expanded and contracted by means of a control wire which is 50 secured to the distal end of the expandable cage.

Accordingly, a catheter featuring a novel [8000] means of lumen expansion at its distal end has been developed. The present invention utilizes an expandable wire mesh tip attached to the distal end of the catheter, wherein the wire mesh tip is expanded at the situs of a stricture in a lumen through which the catheter is being manipulated. A wire mesh material with intrinsic

shape restoring properties is employed as the material of the wire mesh tip, with the wire mesh tip being fabricated to have a default position in an expanded state, and a moveable sheath being utilized as the means to alternatively contain the wire mesh tip in a contracted position.

[0009] A catheter for insertion in the lumen of a vessel according to the present invention will include the elements of a tubular catheter body, a wire mesh tip and means for manipulating the wire mesh tip.

The tubular catheter body is of substantially [0010] tubular shape, open at both ends, has an inner diameter and an outer diameter, a fixed length, and a proximal end and a distal end.

[0011] The wire mesh tip is capable of being configured to have a substantially cylindrical shape of variable dimensions, open at both ends, with the wire mesh tip having a variable diameter, a variable length, and a proximal end and a distal end. The wire mesh tip is attached at its proximal end to the distal end of the catheter body, such that the wire mesh tip and the catheter body are coaxially joined in a lengthwise direction.

[0012] The means for manipulating the wire mesh tip is utilized to move the wire mesh tip back and forth between a contracted position, wherein the tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than the inner diameter of the tubular catheter body, and a contracted position length, and at least one expanded position, wherein the tip is configured to have dimensions of an expanded diameter greater than the contracted diameter and not greater than thirty times the outer diameter of the catheter body, and an expanded position length that is shorter than the contracted position length.

Fig. 1 is a side view of another alternative embodiment of a catheter according to the present invention, with a self-expandable wire mesh tip open at both ends for maximum blood flow.

Fig. 2 is a cross-section view of the catheter of Fig.

[0013] According to the present invention there is provided a catheter as defined in accompanying claim 1.

[0014] The catheter with wire mesh tip allows precise control of the diameter to which the mesh is expanded, thereby eliminating the possibility of over-expansion and possible consequent damage to the vessel.

Another advantage of the catheter and wire [0015] mesh tip system of the present invention is that the system does not totally occlude the blood vessel when the wire mesh tip is expanded. Even in its fully expanded state, blood will continue to flow through the open ended, generally cylindrically-shaped wire mesh tip along a flow path from the outer wall of the catheter to the edge of the wire mesh tip.

[0016] The wire mesh tip of a catheter according to the present invention can be fabricated from any type of

35

wire mesh meterial with a mesh size that has sufficient permeability to allow the flow of blood or whatever fluid is flowing through the vessel in which the catheter is being utilized through the mesh when the tip is in its expanded position, in order that the lumen in which the catheter is being manipulated does not become totally occluded to flow when the mesh tip is in the expanded position.

[0017] The wire mesh material itself can be fabricated from any biologically inert material. It is preferable that the wire be metal, although certain inert plastics having sufficient strength may also be used. Stainless steel, titanium, titanium alloy, nitinol (nickel-titanium alloy), and vitallium alloy are suitable metallic materials of construction of the wire mesh. High molecular weigh polyethylene is a suitable plastic material of construction.

[0018] The wire mesh meterial can be made in a variety of patterns. Braided, woven and knit designs can be utilized as long as the fineness of the mesh size is greater than the molecular size of the fluid to be transmitted therethrough, so that fluid flow is not prevented by the mesh.

[0019] The extent of compression of the flow obstructing meterial in the vessel that is effected by expansion of the wire mesh tip is determined in part by the fineness of the mesh material and the pattern that it forms which is utilized. Thus, if a tightly woven mesh is used, the flow obstructing material will be fairly evenly compressed against the wall of the vessel, whereas if a more loosely woven wire mesh is utilized, compression of the flow obstructing material against the wall of the vessel will occur only where the mesh comes in contact with the material. There will be little or no compression in the interstices between the mesh. In this case, a waffle pattern will be impressed on the flow obstructing material. If the mesh material is sharp, it may cut into the flow obstructing mass causing particles of it to be cut away.

[0020] A wire mesh tipped catheter according to the present invention, utilizes a material for the wire mesh which has intrinsic shape-restoring properties, and the wire mesh tip is fabricated to have a default position in its expanded position. The catheter also includes a control element, which is alternatively a rod, a tube or an open coil which cooperates with the wire mesh tip, and can be alternatively either attached or unattached thereto, and also includes as the means for manipulating the wire mesh tip, a string passed through the open coil, with a portion of the string being woven through the wire mesh tip, such that in order to cause the wire mesh 50 tip to assume its contracted position, the string is pulled in a direction toward the proximal end of the catheter and inside the open coil, thereby causing that portion of the string woven through the wire mesh tip to shorten, and in turn, causing the wire mesh tip to partially contract. This embodiment of the catheter also utilizes a moveable outer sheath, which corresponds essentially to the tubular catheter body incorporating the control

element-late mechanism for manipulating the wire mesh tip. The sheath is capable of surrounding the wire mesh tip, and has a first position, in which the movable outer sheath surrounds the wire mesh tip, and a second position, in which the movable outer sheath does not surround the wire mesh tip, such that upon manipulation of the movable outer sheath in a direction toward the distal end of the catheter, from the second position to the first position of the outer sheath, a remaining uncontracted portion of wire mesh tip is caused to contract further such that the wire mesh tip is movable to its expanded position, first by manipulation of the outer sheath in a direction toward the proximal end of the catheter, from the first position to the second position of the outer sheath, to partially expand the wire mesh tip, by releasing the distal end of the wire mesh tip, and subsequently releasing the string, allowing the intrinsic shape-restoring force of the wire mesh tip to fully expend the proximal end of the wire mesh tip.

[0021] Referring to Figs. 1 and 2, which illustrate this embodiment, the wire mesh of wire mesh tip 2 is bonded to an open coil 23 at a single connection point 26. A "purse string" 18 is inside of the coil and is woven through the wire mesh tip. The diameter of the wire mesh tip is reduced prior to reinserting the tip in the sheath 15 by retracting or pulling back on the purse string in order to contract the wire mesh tip for recovery and removal from the vessel in which it has been deployed. The flow path for fluid flow with the mesh tip in the expanded position is limited to flow channels as shown by X' in Fig. 1. This embodiment is shown in cross section in Fig. 2.

[0022] According to the present invention which utilizes a wire mesh tip fabricated from an intrinsic shape restoring material, and a movable sheath to deploy the wire mesh tip, the wire mesh tip is only a bipositional device, capable of assuming alternatively only a fully contracted or a fully expanded position.

[0023] The wire mesh tip is alternatively fabricated from a single piece of wire mesh which can be joined lengthwise side edge to side edge forming a seam in order to form an open cylindrical tip, or the wire mesh tip can be formed from a plurality of rectangular wire mesh panels, with each panel having a proximal end, a distal end and two sides, the sides being longer than the ends, further with each panel terminating in a forward section having an outwardly facing curvilinear edge, and each panel being longitudinally attached to an adjoining panel on both sides, to form a substantially cylindrical tip.

[0024] According to the present invention, the wire mesh material of the wire mesh tip is fabricated in a braided, woven or knot pattern. The wire mesh material of the wire mesh tip has a mesh size that is permeable to the flow of fluid present in the lumen of the vessel in which the catheter is deployed. The wire mesh of the wire mesh tip is fabricated from a metal or plastic that is inert to fluid present in the lumen of the vessel in which

the catheter is deployed. Such materials include stainless steel, nitinol, titanium, vitallium and polyethylene.

[0025] Depending on the pliability and compressibility of the flow obstructing mass, a vessel in which the effective passageway available for blood flow has been 5 increased by the above procedure may maintain its widened diameter or it may gradually or even acutely return to a stenosed state. In the former case, this occurs by the redeposition of flow obstructing material such as plaque on the walls of the vessel at the same location using the compressed material as a nucleation site for new deposition, or in the latter case by the sudden reexpansion of the compressed mass of material to at or near its original vessel occluding diameter. Occurrence of the latter is particularly undesirable, as it may precipitate acute cardiovascular, particularly coronary, insufficiency resulting in a serious, possibly life-threatening, cardiovascular incident, manifested as a heart attack or stroke.

[0026] In order to prevent the re-occurrence of either type of occlusive condition, it is desirable that the flow obstructing material be removed rather than merely compressed.

[0027] It is known that radio frequency (RF) energy is effective in cutting or ablating plaque deposits on blood 25 vessel walls, and for coagulating tissue.

[0028] Accordingly, certain embodiments of a wire mesh tipped catheter according to the present invention further include a wire for transmitting radio frequency energy. The wire extends the length of the tubular catheter body from the proximal end thereof to the distal end thereof. The wire is positioned in the annulus formed between the other diameter of the inner tubular wall and the inner diameter of the outer tubular wall of the tubular catheter body, the wire being connected at a distal end thereof to the wire mesh tip.

[0029] A source for generating radio frequency energy connected to the wire at a proximal end thereof, external to the proximal end of the tubular catheter body is also provided.

[0030] In one embodiment, the wire for transmitting radio frequency energy is a main transmitting wire which is connected to the wire mesh tip at a plurality of points of attachment on the outer surface of the wire mesh through a corresponding number of branch transmitting wires extending from the main transmitting wire to the points of attachment.

[0031] The RF energy transmitting wire electrodes attached to the wire mesh tip can be either monopolar or bipolar.

[0032] Bipolar electrodes can be utilized with a braided wire mesh by running two leads to two parallel helical elements in the mesh and insulating all other members from those two members, by fabricating all other members of the braided mesh from electrically non-conducting material such as plastic or by providing insulation over the otherwise electrically conductive wires to make them non-conducting. The two parallel

helical members should both be either right hand or left had helixes so that their elements do not cross.

[0033] An advantage of a catheter with wire mesh tip, further provided with an RF energy transmitting electrode attached to the mesh tip, is that it allows the RF energy to be transmitted through all or part of the mesh to cut, ablate or coagulate tissue.

[0034] For angioplasty applications, this allows for the capability of first expanding the mesh tip to compress the restrictive plaque or other mass and then coagulate to seal it in its compressed position to prevent its reexpansion and the restenosis of the vessel.

[0035] In the treatment of benign hypertrophy of the prostate, the system of the present invention with RF energy transmission capability can be utilized in a cutting mode to first expand the mesh tip and then rotate it while applying RF energy to the expanded mesh to cut out a plug of tissue to remove the urethral stricture.

[0036] The apparatus of the present invention, particularly the embodiment incorporating means for applying RF energy to the surrounding tissue can also be utilized in the treatment of percutaneous diskectomy, wherein the expanded wire mesh tip is first used to entrap tissue which is then ablated or cut with the RF energy.

[0037] For the catheter of the present invention, it has been found that the possibility of the occurrence of a thrombosis can be reduced by coating all or part of the catheter and the elements thereof which come in contact with blood in a lumen of a vessel with a non-thrombogenic material, such as heparin or hirudin.

[0038] For all applications, the elements of the catheter, and particularly the wire mesh tip can also be coated with an elastomeric material to facilitate movement of the catheter through the lumen by decreasing any tendency to adhere to the lumen wall. The preferred elastomeric materials include silicone and thermoplastic elastomers, such as extruded and injection-molded elastomers, and particularly polyurethane and polyethylene.

[0039] It has also been found useful in the method of use of the catheter to prime it with one or more of a radiopaque solution to assist in placement of the catheter by monitoring it with an instrument capable of detecting a change in electromagnetic wave penetration; and a saline solution to give the outer surface of said catheter a blood pH compatible coating.

[0040] The method of use of catheters according to the present invention in procedures to remove a mass obstructing the lumen of a vessel to increase flow through the lumen, such as in angioplasty for the removal of plaque, in the treatment of benign hypertrophy of the prostate to remove prostatic tissue causing a urethral stricture, and in the treatment of percutaneous diskectomy to remove tissue, generally includes the steps of inserting the catheter with the wire mesh tip in a contracted position into the lumen of the vessel; advancing the catheter to the situs of the obstruction; expanding the wire mesh tip of the catheter to compress

the obstruction and open the lumen for increased flow therethrough; maintaining the wire mesh tip in the expanded position for a sufficient time to maintain the obstruction in a compressed state so that it will remain compressed after the catheter is withdrawn; optionally utilizing electromagnetic energy such as radio frequency energy to ablate the obstruction; re-contracting the wire mesh tip; and withdrawing the catheter from the lumen.

[0041] The specific method utilized with catheters according to the present invention, the embodiment of which is illustrated in Figs. 1 and 2, is described by the following procedure.

[0042] The catheter is first inserted into the lumen of the vessel to be cleared of an obstruction. The wire mesh tip is fabricated from a wire mesh material having intrinsic shape-restoring properties, with the wire mesh tip being fabricated to have a default position in a second, expanded position thereof. The wire mesh tip cooperates with an open coil, such that the wire mesh tip is initially in a first contracted position wherein the wire mesh tip is configured to have dimensions of a contracted diameter substantially equal to and not greater than the outer diameter of the outer tubular wall of the tubular catheter body, and a contracted position length. In this embodiment, moreover, the tubular catheter body acts as means for manipulating the wire mesh tip between its first and second positions, by functioning as a sheath for the wire mesh tip. The sheath has a first position in which it surrounds the wire mesh tip, and a second position in which it does not surround the wire mesh tip. The wire mesh tip manipulating means further includes a string which passes through the open coil, with a portion of the string being woven through the wire mesh tip, such that in order to cause the wire mesh tip to move from its first position to its second position, the outer sheath is first moved from its first position to its second position, to release the distal end of the wire mesh tip. The string is subsequently released to allow the intrinsic shape-restoring properties of the wire mesh tip to cause the proximal end of the wire mesh tip to fully expand. To cause the wire mesh tip to move from its second position to its first position, the string is first pulled in a direction toward the proximal end of the catheter, to thereby shorten the portion of the string woven through the wire mesh tip, partially contracting the wire mesh tip, and subsequently moving the outer sheath in a direction toward the distal end of the catheter, to move the outer sheath into its first position wherein it surrounds the wire mesh tip, thereby fully contracting the wire mesh tip.

[0043] The catheter is then advanced through the lumen so that the wire mesh tip is at the situs of the flow obstruction.

[0044] The movable outer sheath (tubular catheter 55 body) is then moved proximally to its second position and the string is released to cause the wire mesh tip to expand at the situs of the flow obstruction, such that the

wire mesh tip has an expanded diameter greater than its contracted diameter and less than thirty times the outer diameter of the outer tubular wall of said catheter, and an expanded position length expanding parallel to the axial direction of the catheter that is shorter than the first position length. Expansion of the diameter of the wire mesh tip at the situs of the flow obstruction produces a compression of flow obstructing material against the tubular wall of the lumen to widen the passageway for flow through the lumen.

[0045] Optionally, radio frequency energy supplied from a source external to the catheter and transmitted through at least one transmitting wire to the wire mesh tip to which the distal end of the at least one transmitting wire is attached, is then utilized to energize the wire mesh tip to cut or ablate the flow obstructing material with which the wire mesh tip in its expanded position is in contact.

[0046] Suction through the catheter is also optionally utilized to remove any debris formed during cutting or ablation.

[0047] The movable outer sheath (tubular catheter body) is then moved to its first position to cause the wire mesh tip to be restored to its first, contracted position.

[0048] Finally, the catheter is withdrawn from the lumen.

[0049] According to the method of use of the apparatus of the present invention, an embodiment of a catheter of the present invention is left in place in the lumen of a vessel to compress an obstruction therein and enlarge the flow path through the lumen for at least a sufficient time to cause the obstructed material to remain compressed against the lumen wall. The catheter may be left in place with the wire mesh tip in an expanded position for a period of up to about 48 hours, although that length of time is generally not required to cause a lasting compression of the obstructive material. In those catheters which include means for [0050] delivery of radio frequency energy to the obstruction in order to cut or ablate the mass of obstructive material, radio frequency energy is applied only for a sufficiently long period of time to cut or ablate the material, which is generally not longer than several minutes, although the catheter may be left in position with the wire mesh tip in its expanded position for a longer period of time of up to about 48 hours, in order to continue to compress any remaining obstructive material against the wall of the luman to increase the flow path through the lumen.

[0051] All catheters according to the present invention can also be utilized with and include as an element thereof, a guidewire to facilitate placement of the catheter into the lumen of the vessel and advancement of the catheter to the situs of the obstruction. A guidewire lumen must be provided through the catheter from its proximal to its distal end to accommodate the guidewire. In those embodiments which utilize a control wire-plate mechanism to manipulate the wire mesh tip, the control wire can be a hollow tube and the plate has a hole

45

through it to accommodate the guidewire.

[0052] When a guidewire is utilized, the abovedescribed method of use of each embodiment of catheter equipped with a guidewire is preceded by an intial step, performed before insertion of the catheter into the 5 lumen of the vessel, of inserting the guidewire into the lumen and advancing it through the lumen to the situs of the obstruction with at least a portion of the guidewire remaining erternal to the lumen at the point of insertion. The catheter is then placed on the guidewire and advancement of the catheter in the lumen to the situs of the obstruction according to the above-described methods of use proceeds along the guidewire.

[0053] All embodiments of the catheter according to the present invention can also include means for suctioning debris and fluids from the situs of removal of the obstructive mass through the catheter.

[0054] All embodiments of the catheter according to the present invention which utilize wire mesh tip control means, such as a control element-plate, and wherein 20 the wire mesh tip extends beyond the distal end of the tubular catheter body when the tip is in a contracted position, with the wire mesh tip being unsheathed, can also be fitted with a slidable sheath to cover the wire mesh tip during insertion of the catheter to prevent the 25 wire mesh tip from damaging the lumen of the vessel. Such a sheath is then retracted when the catheter is in place with the wire mesh tip at the situs at the obstruction before the wire mesh tip is expanded, and replaced when the catheter is to be withdrawn.

[0055] When the catheter is to be primed with one or more of a radiopaque contrasting solution to facilitate tracing its location; a saline solution to make it pH compatible with body fluids or blood in the vessel into which the catheter is to be inserted; or is to be created with a non-thrombogenic material to prevent blood clotting, such priming and/or coating steps are performed first, prior to insertion of the catheter into the vessel.

The foregoing embodiments of the wire mesh [0056] tipped catheter, its constituent elements and its method areas of use, according to the present invention, are not intended to be limiting. Further examples within the scope of the claims will be apparent to those skilled in the art.

Claims

1. A catheter (1) for insertion into the lumen of a vessel and comprising a body (23) in the form of a rod, a tube and an open coil having a longitudinal axis 50 and attached to which at a distal end (25) thereof is a wire or plastics mesh tubular tip (2) substantially co-axial with said body (23), said mesh tip (2) having a proximal end attached to said distal end of the body (3) and a distal end which are displaceable longitudinally relative to each other causing the mesh tip (2) to expand diametrically relative to the longitudinal axis for enlarging an effective inner

diameter of the lumen or causing the mesh tip to contract diametrically relative to the longitudinal axis between a fully expanded condition and a contracted condition, said mesh tip (2) having shape restoring properties which provide the tip with a default condition and wherein a sheath (15) is provided on said body (23) and longitudinally movable relative thereto for the mesh tip (2) in its contracted condition to be receivable axially in said sheath (15) to be retained in its contracted condition and control means (15, 23) which controls relative axial displacement between the sheath (15) and the mesh tip (2) whereby the sheath (15) is removable from the tip (2) to permit the mesh tip (2) to expand from its contracted condition, the material of the mesh for said tip (2) having intrinsic shape restoring properties which provide the tip (2) with a default position corresponding to said fully expanded condition whereby in the absence of a restraining force (15, 18) the mesh tip (2) will adopt its fully expanded condition; CHARACTERISED IN THAT a draw string means (18) displaceable longitudinally relative to the body (15) for controlling expansion of the mesh tip (2), woven through the proximal end of the wire mesh tip (2) as a purse string and longitudinal displacement of which draw string relative to the body (15) serves to apply to the mesh tip a restraining force against said shape restoring properties and by which the mesh tip (2) can be contracted to or towards its contracted condition.

- 2. A catheter as claimed in Claim 1 in which the sheath means is displaced axially relative to the mesh tip (2) in a direction axially towards the proximal end of the catheter to cause the mesh tip to adopt, under control of the draw string means (18), an expanded condition from its contracted condition and in an axially opposite direction to cause the sheath to apply the restraining force to the mesh tip for the mesh tip to be restrained in its contracted condition.
- A catheter as claimed in either Claim 1 or Claim 2 in which the control means for effecting the relative axial displacement between the sheath (15) and the mesh tip (2) comprises at least one of a rod, a tube or an open coil (23).
- 4. A catheter as claimed in any one of the preceding claims in which the draw string (18) is carried within a lumen of the body (15).
- 5. A catheter as claimed in any one of the preceding claims in which the mesh tip (2) is fabricated in a braided, woven or knot pattern.
- 6. A catheter as claimed in any one of the preceding claims and comprising a guide wire (17) extending

20

35

40

kann.

axially through a catheter and over which guide wire the catheter (1) can be advanced for facilitating placement of the catheter in the lumen of a vessel.

- 7. A catheter as claimed in anyone of the preceding claims in which the said body (15) has at least part of its outer surface area and said wire mesh tip (2) has at least part of its surface area which is intended to come into contact with body fluid in the lumen of a vessel coated with at least one of a non-thrombogenic material and an elastomeric material.
- 8. A catheter as claimed in Claim 7 in which said elastomeric material is selected from thermoplastics elastomers and silicone.
- 9. A catheter as claimed in Claim 8 in which the thermoplastics elastomers comprise polyurethane and polyethylene.
- 10. A catheter as claimed in anyone of the preceding claims and comprising a wire (8a, 8b) for transmitting electromagnetic energy into flow-obstructing material in the lumen to cause an attenuation of the flow-obstructing material, said wire being carried within a lumen of the body (1) and connected to said mesh tip (2).
- 11. A catheter as claimed in Claim 10 in which said wire (8a, 8b) extends the length of the body of the catheter (1) from a proximal end of said body to its distal end, said wire being positioned in an annulus formed between an inner diameter of the sheath (1, 15) and said body (23).
- 12. A catheter as claimed in either Claim 11 in which said wire (8a, 8b) is connected to the mesh tip (2) at a plurality of points of attachment on the outer surface of the mesh tip (2) through branches extending from said wire (8a, 8b).
- 13. A catheter as claimed in any one of Claims 10 to 12 in combination with a source for generating electromagnetic energy, said source being connected to the wire (8a, 8b) for transmitting electromagnetic energy in the radio frequency range at a proximal end of the wire and being located externally of the sheath (15).

Patentansprüche

1. Katheter (1) zum Einführen in das Lumen eines Gefäßes und umfassend einen Körper (23) in Form einer Stange, ein Rohr und eine offene Wendel mit einer Längsachse und an deren distalem Ende (25) 55 eine röhrenförmige Draht- oder Plastikgeflechtspitze (2) angebracht ist, die im wesentlichen koaxial zu dem Körper (23) ist, wobei die Geflecht-

spitze (2) ein am distalen Ende des Körpers (3) befestigtes proximales Ende und ein distales Ende aufweist, die im Verhältnis zueinander entlang der Längsachse verschiebbar sind, was bewirkt, daß die Geflechtspitze (2) diametrisch relativ zur Längsachse expandiert, um einen effektiven Innendurchmesser des Lumens zu vergrößern oder daß sich die Geflechtspitze diametrisch relativ zur Längsachse zwischen einem vollständig expandierten Zustand und einem zusammengezogenen Zustand zusammenzieht, wobei die Geflechtspitze (2) Formwiederherstellungseigenschaften aufweist, die die Spitze mit einem vorgegebenen Zustand ausstatten und wobei eine Hülle (15) auf dem Körper (23) zur Verfügung gestellt wird und im Verhältnis dazu in Richtung der Längsachse beweglich ist, damit die Geflechtspitze (2) in ihrem zusammengezogenen Zustand axial in die Hülle (15) aufgenomwerden men kann, um in ihrem zusammengezogenen Zustand gehalten zu werden und eine Kontrolleinrichtung (15, 23), die die relative axiale Verschiebung zwischen der Hülle (15) und der Geflechtspitze (2) kontrolliert, wobei die Hülle (15) von der Spitze (2) entfernt werden kann, um der Geflechtspitze (2) das Expandieren aus ihrem zusammengezogenen Zustand zu ermöglichen, wobei das Material des Geflechts für die Spitze (2) immanente Formwiederherstellungseigenschaften aufweist, die die Spitze (2) mit einer vorgegebenen Stellung ausstatten, die dem vollständig expandierten Zustand entspricht, wobei in Abwesenheit einer einschränkenden Kraft (15, 18) die Geflechtspitze (2) ihren vollständig expandierten Zustand einnehmen wird; dadurch gekennzeichnet, daß eine Zugbandeinrichtung (18), die im Verhältnis zum Körper (15) entlang der Längsachse verschiebbar ist, zum Kontrollieren der Ausdehnung der Geflechtspitze (2) als Zuziehband durch das proximale Ende der Drahtgeflechtspitze (2) gewoben ist und wobei ein Verschieben des Zugbands im Verhältnis zum Körper (15) entlang der Längsachse dazu dient, eine einschränkende Kraft gegen die Formwiederherstellungseigenschaften auf die Geflechtspitze auszuüben und wodurch die Geflechtspitze (2) in ihren zusammengezogenen Zustand oder auf ihren zusammengezogenen Zustand hin zusammengezogen werden

2. Katheter nach Anspruch 1, wobei die Hülleneinrichtung axial im Verhältnis zur Geflechtspitze (2) verschoben ist, in einer Richtung, die axial zum proximalen Ende des Katheters verläuft, was bewirkt, daß die Geflechtspitze unter der Kontrolle der Zugbandeinrichtung (18) aus ihrem zusammengezogenen Zustand einen expandierten Zustand annimmt und in einer axial entgegengesetzten Richtung bewirkt, daß die Hülle eine ein-

25

schränkende Kraft auf die Geflechtspitze ausübt, damit die Geflechtspitze in ihrem zusammengezogenen Zustand gehalten wird.

- 3. Katheter nach Anspruch 1 oder 2, wobei die Kontrolleinrichtung, die die relative axiale Verschiebung zwischen der Hülle (15) und der Geflechtspitze (2) bewirkt, zumindest eines von einer Stange, einem Rohr oder einer offenen Wendel (23) umfaßt.
- Katheter nach einem der vorstehenden Ansprüche, wobei das Zugband (18) in einem Lumen des Körpers (15) getragen wird.
- 5. Katheter nach einem der vorstehenden Ansprüche, wobei die Geflechtspitze (2) in einem geflochtenen, gewobenen oder geknüpften Muster gefertigt ist.
- 6. Katheter nach einem der vorstehenden Ansprüche und umfassend einen Führungsdraht (17), der sich 20 axial durch einen Katheter erstreckt und über welchen Führungsdraht der Katheter (1) zum Erleichtern der Plazierung des Katheters im Lumen eines Gefäßes vorwärts bewegt werden kann.
- 7. Katheter nach einem der vorstehenden Ansprüche, wobei zumindest ein Teil der äußeren Oberfläche des Körpers (15) und zumindest ein Teil der Oberfläche der Drahtgeflechtspitze (2), die dazu bestimmt ist, mit Körperfluid im Lumen eines Gefäßes in Kontakt zu kommen, mit zumindest entweder einem nichtthrombenbildenden Material oder einem elastomeren Material überzogen ist.
- 8. Katheter nach Anspruch 7, wobei das elastomere Material ausgewählt ist aus thermoplastischen Elastomeren und Silikon.
- Katheter nach Anspruch 8, wobei die thermoplastischen Elastomere Polyurethan und Polyethylen 40 umfassen.
- 10. Katheter nach einem der vorstehenden Ansprüche und umfassend einen Draht (8a, 8b) zum Übertragen elektromagnetischer Energie in Durchfluß-verstopfendes Material im Lumen, um eine Verdünnung des Durchflußverstopfenden Materials zu bewirken, wobei der Draht in einem Lumen des Körpers (1) getragen wird und mit der Geflechtspitze (2) verbunden ist.
- 11. Katheter nach Anspruch 10, wobei sich der Draht (8a, 8b) entlang der Länge des Katheterkörpers (1) von einem proximalen Ende des Körpers zu seinem distalen Ende erstreckt, wobei der Draht in einem zwischen dem Innendurchmesser der Hülle (1, 15) und dem Körper (23) gebildeten Ring gelagert ist.

- 12. Katheter nach Anspruch 11, wobei der Draht (8a, 8b) an einer Vielzahl von Befestigungspunkten auf der äußeren Oberfläche der Geflechtspitze (2) über Abzweigungen, die sich von dem Draht (8a, 8b) aus erstrecken, mit der Geflechtspitze (2) verbunden ist.
- 13. Katheter nach einem der Ansprüche 10 bis 12 in Kombination mit einer Quelle zum Erzeugen elektromagnetischer Energie, wobei die Quelle mit dem Draht (8a, 8b) zum Übertragen elektromagnetischer Energie im Hochfrequenzbereich an einem proximalen Ende des Drahts verbunden ist und außerhalb der Hülle (15) angeordnet ist.

Revendications

1. Cathéter (1) destiné à être introduit dans la lumière d'un vaisseau et comportant un corps (23) sous la forme d'une tige, un tube et un enroulement ouvert ayant un axe longitudinal et à une extrémité distale (25) duquel est attaché un embout tubulaire (2) en toile métallique ou de matière plastique, sensiblement coaxial audit corps (23), ledit embout (2) en toile ayant une extémité proximale attachée à ladite extrémité distale du corps (3) et une extrémité distale, lesquelles peuvent être déplacées longitudinalement l'une par rapport à l'autre, provoquant une expansion diamétrale de l'embout en toile (2) par rapport à l'axe longitudinal pour agrandir le diamètre intérieur effectif de la lumière, ou provoquant une contraction diamétrale de l'embout en toile par rapport à l'axe longitudinal entre un état totalement expansé et un état contracté, ledit embout (2) en toile ayant des propriétés de reprise de forme qui procurent à l'embout une condition de défaut, et dans lequel une gaine (15) est prévue sur ledit corps (23) et peut être déplacée longitudinalement par rapport à lui pour que l'embout (2) en toile, dans son état contracté, puisse être reçu axialement dans ladite gaine (15) afin d'être retenu dans son état contracté, et un moyen de commande (15, 23) qui commande un déplacement axial relatif entre la gaine (15) et l'embout (2) en toile, grâce à quoi la gaine (15) peut être enlevée de l'embout (2) pour permettre à l'embout (2) en toile de s'expanser à partir de son état contracté, la matière de la toile dudit embout (2) ayant des propriétés intrinsèques de reprise de forme qui procurent à l'embout (2) une position de défaut correspondant audit état totalement expansé, grâce à quoi, en l'absence d'une force de retenue (15, 18), l'embout (2) en toile adopte son état totalement expansé ; caractérisé par un moyen à cordon de traction (18) pouvant être déplacé longitudinalement par rapport au corps (15) pour commander l'expansion de l'embout en toile (2), lacé à travers l'extrémité proximale de l'embout en toile métallique (2) à la manière d'un cordon de bourse, cordon de traction

50

30

35

dont le déplacement longitudinal par rapport au corps (15) sert à appliquer à l'embout en toile une force de retenue à l'encontre desdites propriétés de reprise de forme et par laquelle l'embout en toile (2) peut être contracté dans, ou vers son, état contracté.

- 2. Cathéter selon la revendication 1, dans lequel le moyen à gaine est déplacé axialement par rapport à l'embout en toile (2) dans une direction orientée axialement vers l'extrémité proximale du cathéter pour amener l'embout en toile à adopter, sous la commande du moyen à cordon de traction (18), un état expansé à partir de son état contracté, et dans une direction axialement opposée pour amener la gaine à appliquer la force de retenue sur l'embout en toile pour que l'embout en toile soit retenu dans son état contracté.
- 3. Cathéter selon la revendication 1 ou la revendication 2, dans lequel le moyen de commande pour effectuer le déplacement axial relatif entre la gaine (15) et l'embout en toile (2) comprend au moins l'un d'une tige, d'un tube ou d'un enroulement ouvert (23).
- Cathéter selon l'une quelconque des revendications précédentes, dans lequel le cordon de traction (18) est porté à l'intérieur d'une lumière du corps (15).
- 5. Cathéter selon l'une quelconque des revendications précédentes, dans lequel l'embout en toile (2) est fabriqué dans une configuration tressée, tissée ou nouée.
- 6. Cathéter selon l'une quelconque des revendications précédentes et comportant un fil métallique (17) de guidage s'étendant axialement à travers un cathéter et sur lequel le cathéter (1) peut être 40 avancé pour faciliter la mise en place du cathéter dans la lumière d'un vaisseau.
- 7. Cathéter selon l'une quelconque des revendications précédentes, dans lequel ledit corps (15) a au moins une partie de son étendue de surface extérieure et ledit embout en toile métallique (2) a au moins une partie de son étendue de surface qui est destinée à venir en contact avec un fluide corporel dans la lumière d'un vaisseau, revêtues d'au moins l'une d'une matière non thrombogène et d'une matière élastomérique.
- 8. Cathéter selon la revendication 7, dans lequel ladite matière élastomérique est choisie parmi des élas- 55 tomères thermoplastiques et une silicone.
- 9. Cathéter selon la revendication 8, dans lequel les

élastomères thermoplastiques comprennent un polyuréthanne et un polyéthylène.

- 10. Cathéter selon l'une quelconque des revendications précédentes et comportant un fil métallique (8a, 8b) destiné à transmettre de l'énergie électromagnétique dans une matière formant un obstacle à l'écoulement dans la lumière pour provoquer un amincissement de la matière formant obstacle à l'écoulement, ledit fil métallique étant porté à l'intérieur d'une lumière du corps (1) et connecté audit embout en toile (2).
- 11. Cathéter selon la revendication 10, dans lequel ledit fil métallique (8a, 8b) s'étend sur la longueur du corps du cathéter (1) depuis une extrémité proximale dudit corps jusqu'à son extrémité distale, ledit fil métallique étant positionné dans un espace annulaire formé entre un diamètre intérieur de la gaine (1, 15) et ledit corps (23).
- 12. Cathéter selon la revendication 11, dans lequel ledit fil métallique (8a, 8b) est connecté à l'embout en toile (2) en plusieurs points d'attache sur la surface extérieure de l'embout en toile (2) par l'intermédiaire de ramifications s'étendant depuis ledit fil métallique (8a, 8b).
- 13. Cathéter selon l'une quelconque des revendications 10 à 12, en combinaison avec une source destinée à générer de l'énergie électromagnétique, ladite source étant connectée au fil métallique (8a, 8b) pour transmettre de l'énergie électromagnétique dans la gamme des radiofréquences à une extrémité proximale du fil métallique et étant située à l'extérieur de la gaine (15).

